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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/601,132 | 06/20/2003 | Anthony P. Shuber | EXCT-31012/US-1/PRI | 4962 |
| 72960 7590 03/23/2011 | | | | |
| Casimir Jones, S.C. 2275 DEMING WAY, SUITE 310 MIDDLETON, WI 53562 | | | | |
| EXAMINER AEDER, SEANE | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/601,132

Applicant(s)

SHUBER, ANTHONY P.

Examiner

SEAN AEDER

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-8, 11, 14, 19-21, 24, 28-30 and 35-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1, 4-8, 11, 14, 19-21, 24, 28-30, and 35-40 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-944)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/12/11 has been entered.

Claims 1, 4-8, 11, 14, 19-21, 24, 28-30, and 35-40 are pending.

Claims 1, 14, and 24 have been amended by Applicant.

Claims 1, 4-8, 11, 14, 19-21, 24, 28-30, and 35-40 are currently under consideration.

This Office Action contains New Rejections necessitated by amendments.

Rejections Withdrawn

All previous rejections are withdrawn.

New Rejections Necessitated by Amendments

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-8, 11, 14, 19-21, 24, 28-30, and 35-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **NEW MATTER** rejection.

Claims 1, 14, and 24 recite methods of measuring amounts of nucleic acid fragments amplified from "unfractionated" heterogeneous DNA isolated from supernant from a centrifuged sample comprising a stool sample. Descriptions of methods of measuring amounts of nucleic acid fragments amplified from "unfractionated" heterogeneous DNA isolated from supernant from a centrifuged sample comprising a stool sample are not found in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention. The specification and the originally filed claims do not provide support the negative limitation ("unfractionated") as recited in the claims.

In the Reply of 3/13/11, Applicant indicates [0059]-[0060] of the instant specification provide support for methods of measuring amounts of nucleic acid fragments amplified from "unfractionated" heterogeneous DNA isolated from supernant from a centrifuged sample comprising a stool sample.

The amendments to the claims and the arguments found in the Reply of 3/13/11 have been carefully considered, but are not deemed persuasive. The Examiner does not agree that [059]-[0060] of the instant specification provide support for methods of

measuring amounts of nucleic acid fragments amplified from "unfractionated" heterogeneous DNA isolated from supernatant from a centrifuged sample comprising a stool sample. Rather, [059]-[0060] disclose methods of measuring amounts of nucleic acid fragments amplified from "fractionated" heterogeneous DNA isolated from supernatant from a centrifuged sample comprising a stool sample (see last three lines of [0059], in particular). Specifically, the disclosed method measures amounts of nucleic acid fragments amplified from "fractionated" heterogeneous DNA isolated from supernatant from a centrifuged sample comprising a stool sample wherein the fractionation occurs via: **(1)** a phenol extraction, a phenol/chloroform extraction, a phenol extraction; and **(2)** the DNA would have been fractionated into distinct tubes to perform the amplification reactions. The specification and the originally filed claims do not provide support the negative limitation ("unfractionated") as recited in the claims.

Summary

No claim is allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on 571-272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642